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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,540	02/18/1999	ELFI BIEDERMANN	64978	1192

7590

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 05/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/242,540

Applicant(s)

BIEDERMANN ET AL.

Examiner

Brenda L. Coleman

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 April 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will ~~not~~ be entered ~~because~~:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): see attached Advisory Action.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: 48-50.Claim(s) rejected: 42-47 and 51-86.

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

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ADVISORY ACTION

The shortened statutory period for response expires FIVE MONTHS from the date of the final rejection or as of the mailing date of this advisory action, whichever is later. In no event however, will the statutory period for response expire later than SIX MONTHS from the date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee.

Any extension fee required pursuant to 37 CFR 1.17 will be calculated from the date that the shortened statutory period for response expires as set forth above.

The amendment filed April 11, 2002 under 37 CFR 1.116 in response to the final rejection **has been** considered and **entered**, however the amendment is not sufficient to place the application in condition for allowance.

Response to Amendment

Applicants' amendment April 11, 2002 has been fully considered with the following effect:

1. The applicants' amendments are sufficient to overcome the 35 USC § 112, second paragraph rejection of the last office action labeled paragraph 1, which is hereby **withdrawn**.
2. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 42-46, 56-58, 62, 68, 70 by Goto et al., EP 330 026 (U.S. equivalent 5,169,745) of the last office action, the

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applicants' declaration and arguments have been fully considered but are not found persuasive. The applicants stated that "the '026 reference describes compounds for the treatment of Alzheimer's disease". The claims rejected are not method of use claims but compounds and composition claims. The applicants also stated that the reference "does not describe or suggest the importance of compounds that include a pyridine ring, substitution in the three position, the criticality of "A", or the importance of having an amide group in the chain of the substitution attached to the 3 position as claimed". However, the prior art teaches the substitution of the pyridine ring in the 3 position as well as the "A" substituent and the amide. Hence the prior art teaches that which the applicants urge as critical. The declaration has been considered, however, the species tested are not sufficient in that the variables of '026 are not exemplified.

Claims 42-46, 56-58, 62, 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto et al., EP 330 026 (U.S. equivalent 5,169,745). For reasons of record and stated above.

3. With regards to the obviousness-type double patenting rejections as being unpatentable over copending Application No. 09/216,075 and 09216,482 of the last office action, the applicants stated that they "will file a terminal disclaimer with respect to copending Application No. 09/216,075 and 09216,482 upon notice of allowability.

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Claims 42-46 and 55-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41-47 and 54-79 of copending Application No. 09/216,075. For reasons of record.

Claims 42-46 and 55-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-37 of copending Application No. 09/216,482. For reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. The applicants' amendments are sufficient to overcome the 35 USC § 112, second paragraph rejection of the last office action labeled paragraph 5, which is hereby **withdrawn**.

5. The applicants' amendments are sufficient to overcome the 35 USC § 102, anticipation rejection of the last office action labeled paragraph 6, which is hereby **withdrawn**.

6. With regards to the rejection as being drawn to an improper Markush group, the applicants' arguments have been fully considered but are not found persuasive. The applicants stated that "all pending claims require E to be a piperidine". However, this is not so. Claims 42-44, 56, 64 and 65 are such that E can be azetidine, pyrrolidine, piperidine and azepine, wherein $n + p \leq 3$. In claim 46, E is selected from the group consisting of pyrrolidine, piperidine, hexahydroazepine and morpholine. In claim 68, E is selected from the group consisting of

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pyrrolidine, piperidine, 1,2,5,6-tetrahydropyridine, hexahydroazepine, morpholine and hexahydro-1,4-oxazepine. In claim 71, E is selected from the group consisting of pyrrolidine (see page 62), ethylene bridged piperidine (see pages 65 and 72) and morpholine (see pages 90-92). In claim 77, E is selected from the group consisting of ethylene bridged piperidine (see pages 95 and 101) and morpholine (see pages 119-121). In claim 82, E is selected from the group consisting of ethylene bridged piperidine (see pages 124 and 130) and morpholine (see pages 148-150).

Claims 42-44, 46, 55-65, 68, 71-82 and newly added claims 83-86 are rejected as being drawn to an improper Markush group. For reasons of record and stated above.

7. The applicants' amendments are sufficient to overcome the objection to the specification of the last office action labeled paragraph 9, which is hereby **withdrawn**.

8. The applicants' amendments are sufficient to overcome the 35 USC § 112, first paragraph rejections of the last office action labeled paragraphs 10, 11, 12, 13, 14, 15, 16 and 18, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, first paragraph rejection labeled 17 of the last office action, the applicants' amendments and remarks have been fully considered but they are not persuasive.

17. The applicants stated that the "structures have been deleted which do not have proper antecedent basis". However, the moiety on page 84 where G is -C(=O)-N(isopropyl)₂ has not been deleted. At no time can R¹⁴ of the G group -C(=O)-(CH₂)_r-NR¹²R¹⁴ be isopropyl.

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Claims 71, 77 and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For reasons of record and stated above.

9. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections under paragraph 19 labeled a), b), c), d), e), f), g), h), k), l), m), n), p), r), s), t), v), w), x), y), z), aa), ab), ac), ad), ae), af), ag) and ah) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled i), j), o), q) and u) of the last office action, the applicants' amendments and remarks have been fully considered but they are not persuasive.

- i) The applicants stated that the phrase "bound directly or over a methylene group..." has been rewritten as discussed. However this is not so. See page 18 where the definition of R^{12} in claim 44 still contains the moiety oxodihydrodibenzocycloheptyl bound directly or over a methylene group.
- j) The applicants stated that the "antecedent basis for $-NR^{12}R^{14}$ " in claim 42 has been provided as discussed". However the G group in claim 42 where G is $-C(=O)-(CH_2)_r-NR^{12}R^{14}$ does not permit $-NR^{12}R^{14}$ to form a ring.
- o) The applicants stated that the phrase "bound directly or over a methylene group..." has been rewritten as discussed. However this is not so. See page 22 where the

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definition of R¹² in claim 44 still contains the moiety bound directly or over a methylene group.

- q) The applicants have not provided any arguments with respect to this rejection where claim 47 is dependent upon a canceled claim.
- u) The applicants stated that the phrase “N, S, and O being bound directly to or over a methylene group” has been rewritten as discussed. However this is not so. See page 55 where the definition of R¹² in claim 69 still contains the moiety “the N, S and O being either bound directly to or over a methylene group”.

Claims 44, 45, 47 and 69 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

In view of the amendment dated April 11, 2002, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 10. Claims 64, 72-76 and 85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

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to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where "Q is a nitrogen-containing heterocycle" is not described in the specification. The compounds of formula (I) described in the specification are limited to nitrogen-containing heterocycle bound over the nitrogen atom. Without stating as such the claim includes those nitrogen-containing heterocycles which are bound over a carbon atom.

Applicant is required to cancel the new matter in the reply to this Office action.

11. Claims 71, 77 and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where DEG is $(\text{CH}_2)_6$ -piperidine-SO₂-naphth-2-yl or $(\text{CH}_2)_6$ -piperidine-SO₂-thien-2-yl are not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

12. Claims 83-86 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where two adjacent

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groups of an aromatic ring in the substituted C1-C6-alkoxy may form an additional ring over a methylenedioxy bridge is not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 56-65, 68-70, 72-76, 78-81 and 83-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 56-63 and 84 are vague and indefinite in that it is not known what is meant by "isosterically replaced C₁ to C₁₀ group" on page 28. This has been deleted from independent claims 42, 64 and 65 but not from claim 56.
- b) Claims 64, 72-76 and 85 are vague and indefinite in that it is not known what is meant by "a N, S, O anellated bi- and tricyclic..." on page 37. This has been deleted from independent claims 42, 56, 65 and 69 but not from claim 64.
- c) Claims 65, 78-81 and 86 are vague and indefinite in that it is not known what is meant by "C₁-C₆ alkoxy" which appears twice in the definition of the substituents on the aromatic rings.

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- d) Claim 68 is vague and indefinite in that it is not known what is meant by “isosterically replaced C₁ to C₁₀ group” on page 48. This has been deleted from independent claims 42, 64 and 65 but not from claim 68.
- e) Claim 69 is vague and indefinite in that it is not known what is meant by “isosterically replaced C₁ to C₁₀ group” on page 53. This has been deleted from independent claims 42, 64 and 65 but not from claim 69.
- f) Claim 70 is vague and indefinite in that it is not known what is meant by “isosterically replaced C₁ to C₁₀ group” on page 59. This has been deleted from independent claims 42, 64 and 65 but not from claim 70.
- g) Claim 70 is vague and indefinite in that it is not known what is meant by the moiety “benzyl phenyl” in the definition of R¹² on page 60. It is believed that there should be a comma separating the two moieties.
- h) Claim 70 is vague and indefinite in that it is not known what is meant by “C₃-C₆ alkenyl” which appears twice in the definition of R¹³.
- i) Claims 83-86 are vague and indefinite in that it is not known what is meant by C1-C6 alkoxy.
- j) Claim 84 recites the limitation "a compound" in the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 84 is dependent upon a composition claim, i.e. claim 56.

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- k) Claim 85 recites the limitation "a compound" in the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 85 is dependent upon a method claim, i.e. claim 64.
- l) Claim 86 recites the limitation "a compound" in the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 86 is dependent upon a method claim, i.e. claim 65.

Claim Objections

14. Claims 48-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink that reads "Brenda Coleman". The signature is written in a cursive style with a large, stylized "B" and a long, sweeping underline.

Brenda Coleman
Primary Examiner AU 1624
May 8, 2002